



Food and Drug Administration
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January 30, 2015

Waldenmar Link GmbH & Co. KG
Dr. Thomas Mehler
Director Quality Management
Barkhausenweg 10
22339 Hamburg
Germany

Re: K143179

Trade/Device Name: The LINK[®] Endo-Model[®] Knee System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: November 3, 2014
Received: November 4, 2014

Dear Dr. Mehler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143179

Device Name

The LINK® Endo-Model® Knee System

Indications for Use (Describe)

The LINK® Endo-Model® Knee System is indicated for patients with severe joint diseases with limitation of mobility due to degenerative, rheumatoid or post-traumatic arthrosis or arthritis. Joint fractures which disallow an osteosynthetic reconstruction. This device is intended for cemented use only unless a cementless modular stem is indicated for use.

The LINK® Endo-Model® Rotating Hinge and Modular Rotating Hinge Knee System are indicated for the following conditions:

- 1) Bone necroses.
- 2) Bicondylar arthrosis by partly damaged collateral ligaments
- 3) Revision after primary total knee replacement.
- 4) Revision surgery after hinge knee or rotational knee joint.
- 5) Revision surgery by insufficient / inadequate bone mass.
- 6) Arthrosis of patella flange.
- 7) Valgus/Varus deformities <10°.
- 8) Valgus/Varus deformities 10-15°.
- 9) Valgus/Varus deformities 15-20°.

The LINK® Endo-Model® Non-Rotating Hinge and Modular Non-Rotating Hinge Knee System are indicated for the following conditions:

- 1) Bone necroses.
- 2) Bicondylar arthrosis by completely damaged ligaments and muscular instability.
- 3) Revision after primary total knee replacement.
- 4) Revision surgery after hinge knee or rotational knee joint.
- 5) Revision surgery by insufficient / inadequate bone mass.
- 6) Arthrosis of patella flange.
- 7) Valgus/Varus deformities <10°.
- 8) Valgus/Varus deformities 10-15°.
- 9) Valgus/Varus deformities 15-20°.
- 10) Valgus/Varus deformities 20-30°.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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Date Prepared: November 3rd, 2014

Trade Name: *LINK*® Endo-Model® Knee System

Common Name: Total Knee Prosthesis

Classification Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis; 21 CFR §888.3510, product code KRO

Classification and Panel: Class II, Orthopedic / 87

Predicate Devices: *NexGen*® Complete Knee Solution Rotating Hinge Knee, manufactured by Zimmer, K013385, cleared January 9, 2002

Device Description: The *LINK*® Endo-Model® Knee System is constrained anti-luxation total knee prosthesis. Retaining the low friction principle, the physiological movement of the rotational knee prosthesis is optimal because the pivot point is within the physiological area. Flexion and rotation of the rotational knee prosthesis take place in a cross joint. The *LINK*® Endo-Model® Knee System consists of Femoral and Tibial Components, Modular Stems, Femoral Segments and Proximal Tibial Spacers and Segments. The modular components are interchangeable allowing for independent positioning. The Modular Stems are available in a variety of diameters and lengths in cemented or cementless version. Special Femoral Segments for revision surgery of resurfacing knee implants and for tumor cases are available in a variety of heights. Proximal Tibial Spacers and Segments are used to act as a spacer for the missing bone where surgical reasons require the removal bone.

The *LINK*® Endo-Model® Knee System is available in four (4) different knee joint versions:

- Rotating Hinge Knee – Standard (Non-Modular) Version
- Non-Rotating Hinge Knee – Standard (Non-Modular) Version
- Rotating Hinge Knee – Modular Version
- Non-Rotating Hinge Knee – Modular Version

There are two (2) different versions in the application of the knee system: Rotating and Non-Rotating Hinge version. The main design differences between the Rotating and Non-Rotating Hinge version are the two (2) different mechanical connections between the femoral and the tibial component and the consequent movement of these components. These two (2) different connections are necessary because of the different biophysical properties of the human body and the different indications and contraindications for the use of these products.

The *LINK*® Endo-Model® Knee System is produced of Cobalt Chromium Molybdenum casting alloy (CoCrMo) and Ultra high molecular weight polyethylene (UHMWPE / non-crosslinked). The Modular Stems (cemented) are made of Cobalt Chromium Molybdenum casting alloy (CoCrMo) materials. The Modular Stems (cementless) are made of Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V) materials. Femoral Segments, Proximal Tibial Spacers and Segments are produced of Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V). There are also Proximal Tibial Spacers which were made of Ultra high molecular weight polyethylene (UHMWPE / non-crosslinked). Centralizers and Patella components are made of Ultra high molecular weight polyethylene (UHMWPE / non-crosslinked).

All components are sterile and for single use only.

Indications for Use:

The *LINK*® Endo-Model® Knee System is indicated for patients with severe joint diseases with limitation of mobility due to degenerative, rheumatoid or post-traumatic arthrosis or arthritis. Joint fractures which disallow an osteosynthetic reconstruction. This device is intended for cemented use only unless a cementless modular stem is indicated for use.

The *LINK*® Endo-Model® Rotating Hinge and Modular Rotating Hinge Knee System are indicated for the following conditions:

- 1) Bone necroses.

- 2) Bicondylar arthrosis by partly damaged collateral ligaments
- 3) Revision after primary total knee replacement.
- 4) Revision surgery after hinge knee or rotational knee joint.
- 5) Revision surgery by insufficient / inadequate bone mass.
- 6) Arthrosis of patella flange.
- 7) Valgus/Varus deformities <10°.
- 8) Valgus/Varus deformities 10-15°.
- 9) Valgus/Varus deformities 15-20°.

The *LINK*® Endo-Model® Non-Rotating Hinge and Modular Non-Rotating Hinge Knee System are indicated for the following conditions:

- 1) Bone necroses.
- 2) Bicondylar arthrosis by completely damaged ligaments and muscular instability.
- 3) Revision after primary total knee replacement.
- 4) Revision surgery after hinge knee or rotational knee joint.
- 5) Revision surgery by insufficient / inadequate bone mass.
- 6) Arthrosis of patella flange.
- 7) Valgus/Varus deformities <10°.
- 8) Valgus/Varus deformities 10-15°.
- 9) Valgus/Varus deformities 15-20°.
- 10) Valgus/Varus deformities 20-30°.

Comparison to Predicate Device:

The *LINK*® Endo-Model® Knee System is substantially equivalent to the commercially available device NexGen® Rotating Hinge Knee (RHK) in that both have similar indications, design (both are constrained, rotating hinge knee prostheses), materials and mechanical safety. Both devices are intended for cemented use only.

Performance Data:

Non-Clinical Performance and Conclusions:

Non-Clinical performance testing was conducted with consideration to *Draft Guidance For The Preparation of Premarket Notifications (510(k)s) for cemented, semi-constrained Total Knee Prostheses, April 1993 and Guidance Document for Knee Joint patellofemoral and femorotibial metal/polymer porous-coated uncemented Prostheses, January 16, 2003*

Non-clinical performance testing included: Tibial Bearing Component wear tests per ISO 14243-1 and -2; Tibial Baseplate Component fatigue tests per ISO 14879 and ASTM F1800 and Modular Connections, Fretting, and Corrosion Testing per ASTM F1875-98, Tibiafemoral and Patellofemoral contact area / stress analyses at different

angles of flexion and Range of Motion analysis of the Endo-Model® Rotating Hinge Knee System.

Constraint testing is not applicable to a constrained prosthesis. This test was not necessary.

All Endo-Model® Rotating Hinge Knee System test samples completed the 10 million cycles Tibial Baseplate Fatigue Strength testing without evidence of fracture or cracking.

The results of non-clinical performance testing demonstrated that the device is as safe, as effective, and substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

There was no clinical performance testing required for this device.

Conclusion:

The subject *LINK*® Endo-Model® Knee System is substantially equivalent to the predicate devices identified in this premarket notification.